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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,345	07/28/2000	Claudio Cavazza	2801-21	3925

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EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/29/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/628,345

Applicant(s)

CAVAZZA, CLAUDIO

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/446,806.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on May 19, 2003 have been received and entered into the application.

Applicant's arguments filed on May 19, 2003 have been fully considered but they are not persuasive. Applicant argues that while the effects of the statins generally and the effects of alkanoyl L-carnitines generally are known relative to lipid metabolism, there is no suggestion in the art to combine these two or administer them in a coordinated manner to mitigate the potentially toxic or unwanted side effect-causing results of high dosage statins and thereby allow the clinician to use a lower dose of the statin while achieving the same or substantially the same therapeutic benefit. This is not persuasive since it is admitted by the Applicant that the general effects of statins and the generally effects of alkanoyl L-carnitines are known relative to lipid metabolism, therefore it would have been obvious to one of ordinary skill in the art to combine both active agents to achieve at least an additive effect in the treatment of lipid metabolism. Applicant is combining two components that are known to have same utility. It is well settle in the patent law that the compounds known to have common utility are generally combined in a single composition (see *In re Kerkhoven*, 205 USPQ 1069 (CCPPA 1980)). Further, there is no data showing Applicant's allegation of any of "alkanoyl L-carnitines in combination of statin" in a coordinated manner to mitigate the potentially toxic or unwanted side effect-causing results of high dosage statins and thereby allow

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the clinician to use a lower dose of the statin while achieving the same or substantially the same therapeutic benefit.

In view of the above Office Action of November 20, 2002 is deemed proper and asserted with full force and effect herein to obviate applicant's claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission.

Applicant admits at page 2, lines 11-20 that the statins (lovastatin, simvastatin, provastatin, fluvastatin and the like) reduce the hepatic synthesis of cholesterol.

Applicant also admits at page 3, line 22 through page 4, line 1, that the antitriglyceridaemic and anticholesterolameic effect of a number of **alkanoyl** carnitines, especially acetyl L-carnitine is well known.

The claims differ from the cited references in claiming combination of the alkanoyl carnitine and the statin to treat disorders associated with abnormal lipid

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metabolism. To incorporate the alkanoyl L-carnitine with the statin to treat disorders associated with abnormal lipid metabolism would have been obvious because the antitriglyceridaemic and anticholesterolameic effect of a number of **alkanoyl** carnitines are well known. It would be expected that the combination of any **alkanoyl** carnitines with any statin components would lower lipid conditions as well.

The skilled artist would have been motivated to combine above active agents with reasonable expectation of success to treat disorders associated with abnormal lipid metabolism. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)).

The amounts of active agents to be used set forth in claim 28, the dosing schedules set forth in claims 29 and 31 and optionally adding an excipient set forth in claims 30 and 32 are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

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None of the claims are allowed.

It is suggested that Applicants submit a declaration to clearly establish a surprising and unexpected result using Applicants teaching.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

7/28/03

jmk
July 21, 2003